



**caBIG**

*cancer Biomedical  
Informatics Grid*



**Cancer Biomedical Informatics Grid (caBIG)  
CTMS Best Practices  
Special Interest Group Charter**

**Version 1**

***November 8, 2005***

**Special Interest Group:** Best Practices  
**Document Number:** Version 1

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## CTMS Best Practices Special Interest Group Charter

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### Document Change Record

Version Number	Date	Description
0.1	10/11/2005	Initial Draft and it is discussed at the 1 <sup>st</sup> SIG meeting
0.2	11/8/2005	1. Incorporated suggestions from the SIG members 2. Edited Membership & Responsibilities, membership table, and added Appendix C
1	11/8/2005	1. Separated out the members list. 2. Charter approved by the BPSIG



## **CTMS Best Practices Special Interest Group Charter**

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### **Approval**

This charter is effective upon the date of approval and issuance. Any questions, comments, suggestions or requests for further information should be directed to Andrea Hwang or Jieping Li.

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The BPSIG approved the Charter Version 1

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Date: 11/8/2005

## **Clinical Trial Management System Best Practices SIG Charter**

### **Purpose**

The Clinical Trial Management System (CTMS) Best Practices Special Interest Group (BP SIG) will focus on establishing and fostering relevant clinical trial management best practices for the caBIG™ community. Best practices will support clinical research activities, such as:

- Protocol administration
- Participants registry
- Technology neutral best practices and protocol life-cycle processes for the conduct of a clinical research trials
- Data migration (for legacy clinical trial data)

The CTMS BP SIG will complement, but not overlap, with best practice groups in other caBIG™ Workspaces. The CTMS BP SIG will aim to harmonize best practices within the area of cancer clinical trial management.

For the purpose of this Special Interest Group, a Best Practice is defined as a technique or methodology that, through experience and research, has proven to be reliable in leading to a desired result. The identification and possible adoption of Best Practices can be presented to the group from member experiences or developed as a combination of proven techniques or processes.

### **Background**

The CTMS Best Practices SIG was established in response to multiple requests from the 2005 caBIG™ Annual Meeting to meet the need for an expanded forum for addressing best practices important to the CTMS Workspace participants in the conduct of clinical research trials.

### **Objectives**

- Solicit active membership in the CTMS BP SIG from:
  - All areas within the caBIG™ community
  - Expand participation to include pharma, biotech, vendors, and government partners
  - Participants who are 'domain experts' in the area of clinical research trials

## **CTMS Best Practices Special Interest Group Charter**

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- Participants who are interested in contributing to the success of this new SIG
- Offer guidance and disseminate best practices for implementing CTMS workspace tools to
  - Facilitate **standardization of best practices**
  - Assure the **veracity and authenticity of data** collected in clinical research trials
- Continue to develop SOPs for clinical research trials through the SOP Working Group.
- Provide a forum for identifying additional areas of interest and sharing solutions that are relevant to all CTMS Workspace participants. As the SIG identifies new areas of interest, other Working Groups will be established under this SIG.

### **Scope and Applicability**

All Best Practices, once approved by the BP SIG, will be made available to all of the caBIG™ community and the general public. The best practices developed and recommended by this SIG will not be mandatory for acceptance by the caBIG™ participant sites. However, as a representation of a collective domain expertise, it is recommended that the best practices and accompanying supporting documentation (i.e., SOPs) be considered for adoption by all caBIG™ participant sites as a way to ensure standardization and authenticate results of cancer research trials.

### **Authority**

*Define the authority which is vested in the SIG and individual members.*

- Solicit participation from Domain Experts in other CTMS SIGs, caBIG Workspaces, and from representative industry and academic partners
- Define and develop the documentation of Best Practices for cancer clinical research trials
- Develop templates and learning tools to facilitate adoption of Best Practices by participating caBIG™ sites
- Approve SOPs for the participating caBIG™ sites
- Update existing approved SOPs as science and processes evolve

## **CTMS Best Practices Special Interest Group Charter**

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### **Membership and Responsibilities**

*The table below describes the roles and responsibilities of the Best Practice SIG.*

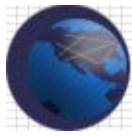
<b>Member</b>	<b>Responsibilities</b>
Co-chairperson (caBIG-affiliated members)	<ul style="list-style-type: none"> <li>• Provide strategic direction to the CTMS BP SIG</li> <li>• Ensure the CTMS BP SIG adheres to NIH and NCI Policies and guidelines</li> <li>• Approve agenda items (including meeting minutes)</li> <li>• Schedule and facilitate meetings</li> <li>• Bring the body to vote once the appropriate level of discussion on particular issues have been reached</li> </ul>
Best Practices SIG members	<ul style="list-style-type: none"> <li>• Responsible for achieving group objectives</li> <li>• Approve CTMS BP SIG decisions</li> <li>• Approve meeting minutes</li> <li>• Support Working Group activities, such as <ul style="list-style-type: none"> <li>• Review and provide input on the SOPs and processes developed to support the SOP Working Group operations by the agreed upon time frame</li> <li>• Review SOPs reported out by the SOP Working group; Approve SOPs for implementation by those adopting cancer center sites.</li> </ul> </li> </ul>
Scribe	<ul style="list-style-type: none"> <li>• Record the meeting minutes</li> </ul>
Liaisons to other CTMS SIGs	<ul style="list-style-type: none"> <li>• Facilitate the communication between the BIP SIGs and other CTMS SIGs.</li> </ul>

## **CTMS Best Practices Special Interest Group Charter**

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### **Operating Procedures**

1. The Best Practices SIG will meet, at a minimum, on a monthly basis, with special meetings called by the Chairperson, as needed. The meetings shall be conducted in accordance with Robert's Rules of Order, which are summarized in Appendix B.
2. The Best Practices SIG will maintain a roster of all participants/members.
3. An agenda for each Best Practices SIG meeting will be prepared and posted to the caBIG™ website (<https://cabig.nci.nih.gov/workspaces/CTMS/>) prior to the meeting date.
4. Best Practices SIG members vote on key topics and issues related to the development and management of the Clinical Trials Best Practices.
  - The Best Practices SIG is a consensus-driven body, where consensus is recognized as majority vote. Each member is allocated one vote. In the event of an impasse, the Best Practices SIG Co-Chairs cast the deciding vote(s)
  - A simple majority vote is required for approving a recommended action or position. Silence/absence is interpreted as approval/agreement.
  - If a member is aware of a topic to be discussed in an upcoming meeting, he or she may give his or her vote in writing to either the chairperson or vice chairperson in advance of the meeting. Such a vote shall be accompanied with an explanation of the person's position. The vote will be included in the meeting notes for the SIG.
  - At the discretion of the Best Practices SIG Co-chairs, a vote via e-mail may be conducted after the scheduled meeting.
5. Meeting minutes will be prepared to document issues addressed and decisions made by the Best Practices SIG. These minutes will be posted to the caBIG™ website (<https://cabig.nci.nih.gov/workspaces/CTMS/>)
6. Best Practices SIG will establish performance objectives and timeframes for completing designated activities that are aligned with the goals and objectives for the user Group.
7. Best Practices SIG members are expected to complete assigned tasks by the agreed upon date in order to keep the group activities moving forward and meet group objectives.
8. The Best Practices SIG Co-Chairs will track the costs, schedule and risks associated with user group activities and assure that corrective actions are taken in a timely manner to mitigate identified risks.



## **CTMS Best Practices Special Interest Group Charter**

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### **Appendix A: Introduction to Robert's Rules of Order<sup>1</sup>**

*Robert's Rules of Order* is a set of rules for conducting meetings, allowing everyone to be heard, while being able to make decisions without confusion. This methodology is a time-tested method of conducting business at meetings and public gatherings. It can be adapted to fit the needs of any organization.

Organizations using this procedure usually follow a fixed order of business. Below is a typical example:

1. Call to order
2. Roll call of members present
3. Reading of minutes of last meeting
4. Officers reports
5. Committee reports
6. Special orders --- Important business previously designated for consideration at this meeting
7. Unfinished business
8. New business
9. Announcements
10. Adjournment

Meeting participants engage in discussions or interact in the form of a moving motion – a proposal that the entire membership take action or a stand on an issue. Individual members can make a motion to: (1) call the group to order; (2) second a motion; (3) debate a motion; or (4) vote on a motion. There are four Basic Types of motions:

1. Main Motions: Introduce items to the membership for their consideration. They cannot be made when any other motion is on the floor, and yield to privileged, subsidiary, and incidental motions.
2. Subsidiary Motions: Change or affect how a main motion is handled. Subsidiary motions are voted on before the main motion.
3. Privileged Motions: Initiate items that are special or important matters unrelated to pending business.
4. Incidental Motions: Provide a means of questioning procedures concerning other motions and must be considered before the other motion.

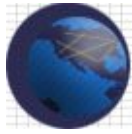
### **How are Motions Presented?**

1. Obtaining the floor:
  - a. Wait until the last speaker has finished
  - b. Address the Chairperson by saying, "Mr. (or Ms.) Chairperson"
  - c. Wait until the Chairperson recognizes you
2. Make your motion
  - a. Speak in a clear and concise manner
  - b. Always state a motion affirmatively. Say, "I move that we..." rather than, "I move that we do not..."
  - c. Avoid personalities and stay on your subject

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<sup>1</sup> General Henry M. Robert, *Robert's Rules of Order* (1915). Public Domain.





## **CTMS Best Practices Special Interest Group Charter**

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3. Wait for Someone to Second Your Motion
4. Another member will second your motion or the Chairperson will call for a second
5. If there is no second to your motion it is lost
6. The Chairperson states your motion
  - a. The Chairperson will say, "It has been moved and seconded that we..." placing your motion before the membership for consideration and action
  - b. The membership then either debates your motion, or may move directly to a vote
  - c. Once your motion is presented to the membership by the chairperson it becomes "assembly property", and cannot be changed by you without the consent of the members
7. Expanding on Your Motion
  - a. The time for you to speak in favor of your motion is now, rather than at the time you present it
  - b. The mover is always allowed to speak first
  - c. All comments and debate must be directed to the chairperson
  - d. Keep to the time limit for speaking that has been established
  - e. The mover may speak again only after other speakers are finished, unless called upon by the Chairperson
8. Putting the question to the membership
  - a. The Chairperson asks, "Are you ready to vote on the question?"
  - b. If there is no more discussion, a vote is taken
  - c. On a motion to move the previous question may be adapted

### **Voting on a Motion:**

The method of vote on any motion depends on the situation and the by-laws of policy of your organization. There are five methods used to vote by most organizations, they are by:

1. Voice - The Chairperson asks those in favor to say, "aye", those opposed to say "no". Any member may move for an exact count.
2. Roll Call - Each member answers "yes" or "no" as his name is called. This method is used when a record of each person's vote is required.
3. General Consent - When a motion is not likely to be opposed, the Chairperson says, "If there is no objection..." The membership shows agreement by their silence, however if one member says, "I object," the item must be put to a vote.
4. Division - This is a slight verification of a voice vote where members raise their hand or stand. It does not require a count unless the chairperson so desires.
5. Ballot - Members write their vote on a slip of paper or via e-mail, this method is used when secrecy is desired

There are two other motions that are commonly used that relate to voting:

1. Motion to Table - This motion is often used in the attempt to "kill" a motion. The option is always present, however, to "take from the table", for reconsideration by the membership

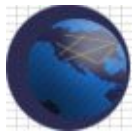
### **CTMS Best Practices Special Interest Group Charter**

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2. Motion to Postpone Indefinitely - Used as a means of parliamentary strategy to allow opponents of a motion to test their strength without an actual vote. Also, debate is once again open on the main motion

The aforementioned procedures are a sound way to conduct meetings; however, the process will only work if it is used properly:

1. Allow motions that are in order
2. Have members obtain the floor properly
3. Speak clearly and concisely
4. Obey the rules of debate
5. Most importantly, BE COURTEOUS



## CTMS Best Practices Special Interest Group Charter

### Appendix B: SOP Review Procedure

The flow chart illustrates the SOP review procedure within the BP SIG.

The SOP Working Group will vote and approve the SOPs. When SOPs are approved on Tuesday afternoon, it will be sent to the BP SIG for review on Thursday (same week – 4th week of the month); and SOP WG expect to receive the feedback from BP SIG before COB of the following Friday (1st week of the following month). Then, the revised version will be sent to the BP SIG before the BP SIG meeting (2nd Tuesday of the following month).

